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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,283	09/01/2005	Joaquin Bigorra Llosas	C 2743 PCT/US	8759
23657 COGNIS CORI	7590 03/14/200 PORATION	EXAMINER		
PATENT DEPA			PALENIK, JEFFREY T	
300 BROOKSIDE AVENUE AMBLER, PA 19002			ART UNIT	PAPER NUMBER
			1615	
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			03/14/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)			
	10/532,283	BIGORRA LLOSAS ET AL.			
Office Action Summary	Examiner	Art Unit			
	Jeffrey T. Palenik	1615			
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address			
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period w. - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	lely filed the mailing date of this communication. (35 U.S.C. § 133).			
Status					
Responsive to communication(s) filed on <u>31 Ja</u> This action is FINAL . 2b)⊠ This Since this application is in condition for allowar closed in accordance with the practice under E	action is non-final. nce except for formal matters, pro				
Disposition of Claims					
4) ☐ Claim(s) 12,13 and 15-20 is/are pending in the 4a) Of the above claim(s) is/are withdrav 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 12,13 and 15-20 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/or Application Papers 9) ☐ The specification is objected to by the Examine 10) ☐ The drawing(s) filed on is/are: a) ☐ access	vn from consideration. relection requirement.	Examiner.			
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.					
Priority under 35 U.S.C. § 119					
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.					
Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 21 April 2005.	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:	ite			

DETAILED ACTION

Response to Remarks

The Examiner thanks the Applicants for their timely reply filed on 19 December 2007, in the matter of 10/532,283.

Applicant's arguments filed 31 January 2008 have been fully considered but they are not persuasive.

Applicant's election with traverse of Group I, claims 12-20 is acknowledged. The traversal is on the belief that "the Claims of Groups I, II and III are linked as inventive composition and inventive method and submethod of making such composition, thus sharing a general inventive concept". This is not found persuasive because the independent claim 12 is directed towards a surface active-preparation that reads on the composition depicted in Example 1 of WO 95/14076.

Per PCT Rule 13.1, the international application shall relate to a group of inventions so linked as to form a single general inventive concept or a "unity of invention" (see MPEP 1850). Per PCT Rule 13.2, said "unity of invention" is fulfilled by defining a special technical feature that is shared amidst the claimed inventions. The Rule further specifies that "[t]he expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art."

Applicant's species election for "alkyl amidobetaines" is also acknowledged.

Therefore, the requirement is still deemed proper and is therefore made **FINAL**.

Claims 14 and 21-32 are withdrawn from further consideration pursuant to 37

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CFR 1.142(b), as being drawn to a non-elected invention and species, there being no allowable generic or linking claim. Since claim 14 is directed to alkyl betaines as opposed to the elected species, it is summarily withdrawn as being directed to non-elected subject matter.

Applicant timely traversed the restriction (lack of unity) requirement between the method for surface treating particles and the method for preparing an inhalation formulation.

The remaining claims 12, 13 and 15-20 are presented and represent all claims under consideration.

Information Disclosure Statement

An Information Disclosure Statement, filed 21 April 2005, is acknowledged and has been reviewed.

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: Concentrated, Low-viscosity, Alkali Metal Sulfate, Surface-active Agent Preparations.

Claim Objections

Claim 15 objected to because of the following informalities: the general formula (II) provided in the claim shows the (R₅) and (R₆) groups branching from the compound between the nitrogen and –CH₂- groups. This is recognized as a typographical error. Appropriate correction is required.

Claims 19 and 20 are objected to because of the following informalities: the viscosity units are not clearly stated in the claims. Both claims recite "mPas" as the units. This interpreted herein by the Examiner to mean "millipascal seconds". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 recites the limitation "the quantities" in line 4 of the claim. There is insufficient antecedent basis for this limitation in the claim.

The recitation "the quantities add up to 100% by weight with water" and "optionally other electrolyte salts" render the claim indefinite. Since components (a) and (b), at most, comprise 55% of the composition, it is unclear what other components or amounts of other components comprise the remaining 45% of the composition.

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The remaining claims are rejected since they depend from claim 12.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 12, 13, 15-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Bednall et al. (WO 95/14076).

The instant claims are directed towards a surface-active composition (e.g. a surfactant) comprising (a) an amphoteric or zwitterionic surfactant between 25-50% by weight and (b) at least one alkali metal sulfate between 0.01-5% by weight. The proviso set forth in the instant claim 12 is interpreted to mean that the quantities of the components added to create the composition represent 100% of said composition and that water is included as one of said components. Dependent claim 13, in accordance with the aforementioned species election, further limits the composition of claim 12 such that the surfactant is an alkyl amidobetaines. Dependent claim 15 recites the following general formula (II):

$$\begin{matrix} R^6 \\ | \\ R^4 CO-NH-(CH_2)_{q_3}-N-(CH_2)_{q_2}COOZ \\ | \\ R^5 \end{matrix}$$

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Given the aforementioned objection, the compound is interpreted to be:

Claim 15 further specifies limitations to R₄, R₅, R₆, q₂ and q₃. The alkali metal sulfate is limited to either or a mixture of sodium sulfate and potassium sulfate in claim 16 and further limited to sodium sulfate in claim 17. Claim 18 further limits the percent range of sodium sulfate. Claims 19 and 20 further limit claim 12 such that the composition is measured to be within a certain viscosity range.

Bednall et al. teach in Example 1, the preparation of the alkyl amidobetaine cocoamido propyl betaine (CAPB), which has the following structural formula:

The limitations of the structure are met: R_4 is a C_{11} group, R_5 and R_6 are both methyl groups, q_2 is equal to 1, and q_3 is equal to 3. The CAPB active matter measures 40.2% w/w, sodium sulfate measures 0.3% w/w and contains water as well as the electrolyte sodium chloride (page 18). As to the viscosity range limitations recited in claims 19 and 20, since Example 1 teaches the composition as claimed, the claimed viscosity ranges are, therefore, inherently anticipated. MPEP 2112 states that "the fact

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that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention." Therefore each and every element of the claims is met by the reference.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 12-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bednall et al. (WO 95/14076).

The instant claims are directed towards a surface-active composition, as described above. Also, as described above claim 19 recites the composition as having a measured viscosity of less than 5,000 mPa-seconds and claim 20 recites the composition as having a measured viscosity ranging from 1,000 to 2,500 mPa-seconds. Bednall et al. teaches

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that the compositions of his invention typically have a viscosity of "most preferably 700 to 6,000 centipoise at ambient temperature" (pg. 15, second paragraph under "Viscosity Characteristics"). A centipoise is equal to one millipascal-second (mPa·s) in SI units (1 $cP = 10^{-2} P = 10^{-3} Pa·s$). Centipoise is properly abbreviated cP, but the alternate abbreviations cps and cPs are also commonly seen.

The reference does not teach the particular viscosity ranges claimed by Applicants. The particular viscosity of a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize.

Optimization of such parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to adjust the components of the claimed surfactant formulation (e.g. water) to obtain the optimal viscosity value in order to best achieve the desired results of the instant invention. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of compositional viscosity would have been obvious at the time of Applicant's invention.

No claims are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey T. Palenik whose telephone number is (571) 270-1966. The examiner can normally be reached on 7:30 am - 5:00 pm; M-F (EST).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-

8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call

800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey T. Palenik/ Examiner, Art Unit 1615 /Michael P Woodward/ Supervisory Patent Examiner, Art Unit 1615